

EMORD & ASSOCIATES, P.C.

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SUITE 600

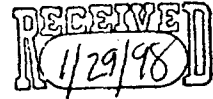
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January 28, 1998 1 7 8 2 '98 FEB 18 A8:59



VIA UPS NEXT DAY AIR

Dr. Elizabeth Yetley
Office of Special Nutritionals (HFS-450)
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

***Re: Fulfillment of Reporting Obligation
Under 21 U.S.C. § 343(r) and 21 CFR § 101.93***

Dear Dr. Yetley:

Pure Encapsulations, Inc.,¹ by counsel and in accordance with 21 U.S.C. § 343(r) and 21 CFR § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Pure Encapsulations retains scientific documentation supporting the statements.

1. Supplement Brand Name

Phosphatidylserine

Text of Statements of Nutritional Support

Phosphatidylserine is a phospholipid found in all cells, but is most concentrated in brain cells.

This familiarly-called "brain nutrient" improves cognitive function, emotional well-being and behavioral performance by restoring cell membrane composition.

Phosphatidylserine is a well-tolerated way to restore phospholipid balance of cell membranes, positively affecting mental activity.

¹ The address for Pure Encapsulations is 490 Boston Post Road, Sudbury, Massachusetts 01776.

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2. **Supplement Brand Name**

Green Tea Extract

Text of Statements of Nutritional Support

Decaffeinated green tea extract counteracts damaging lipid peroxidation and enhances antioxidant enzyme activity.

This concentrated extract contains a high catechin content, providing potent antioxidant support for all cells in the body.

3. **Supplement Brand Name**

Silymarin

Text of Statements of Nutritional Support

Silymarin is a milk thistle extract that nutritionally supports liver function.

This highly active botanical formula protects the liver from free radical damage, increasing glutathione concentrations and superoxide dismutase activity.

Milk thistle extract also stimulates protein synthesis, resulting in the regeneration of hepatic cells and new liver tissue.

Silmarin is a highly concentrated milk thistle extract which supports proper liver functioning through a number of mechanisms.

4. **Supplement Brand Name**

Hawthorn

Text of Statements of Nutritional Support

Hawthorn extract provides nutritional support for the proper functioning of the cardiovascular system.

This herbal formula improves coronary flow, preserves and protects heart tissue, and increases the strength of myocardial contractions.

Hawthorn offers a natural way to enhance and strengthen cardiovascular health.

5. Supplement Brand Name

Ginger

Text of Statements of Nutritional Support

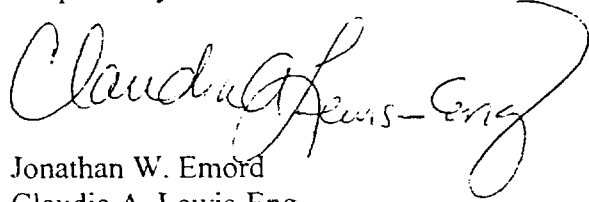
Ginger helps to stimulate digestive enzymes and increases the production and secretion of bile from the liver and gall bladder.

Ginger supports the cardiovascular system by inhibiting leukotriene and thromboxane synthesis, substances associated with platelet aggregation.

This standardized extract provides nutritional support for the digestive and circulatory systems.

In accordance with 21 USC § 343(r)(6) and 21 CFR § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."**

Respectfully submitted

A handwritten signature in cursive script, appearing to read "Jonathan W. Emord" and "Claudia A. Lewis-Eng" joined together.

Jonathan W. Emord
Claudia A. Lewis-Eng

Certification

I, Ray Hamel, General Manager of Pure Encapsulations, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Pure Encapsulations has substantiation that the statements are truthful and not misleading.

Executed on: 1/28/98

Raymond F. Hamel